UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ASTELLAS INSTITUTE FOR REGENERATIVE MEDICINE, *Plaintiff*, v. IMSTEM BIOTECHNOLOGY, INC., XIAOFANG WANG, and REN-HE XU, *Defendants*.	C.A. NO. 1:17-cv-12239 ADB **Leave to File Granted on June 15, 2021 (D.I. 271)**

DEFENDANTS' SUR-REPLY TO ASTELLAS' MOTION FOR ENTRY OF PROPOSED JUDGMENT AND FOR ADDITIONAL FINDINGS AND CONCLUSIONS CONCERNING MASSACHUSETTS GENERAL LAWS, CHAPTER 93A

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I. INTRODUCTION

Astellas accuses (D.I. 268 at 7) ImStem of "turnabout tactics" by pointing to differences between the '551 patent's claims and the PCT application's claims when, supposedly, ImStem had equated those claims earlier in the case. But the accusation rests on an inaccurate description of ImStem's earlier statement, which equated only the specifications and figures of the '551 patent and the PCT application, not their claims: the "PCT Application was the basis for the '551 national stage and thus has the ***same specification and figures*** as the '551 patent." D.I. 247-1 ¶ 134 (emphasis added). Inventorship requires a claim-by-claim analysis, and Astellas' delay in raising applications and patents beyond the '551 patent until after the FFCL prevented the parties and the Court from conducting that analysis.

Astellas' other arguments are similarly unpersuasive. For example, Astellas urges the Court to reconsider its finding of a lack of injury for purposes of Chapter 93A, without pointing to any new evidence that would justify such reconsideration. And Astellas ignores several of ImStem's arguments, such as that the thirty-month deadline for a change of inventorship on the PCT application expired years ago, and that it is premature to attempt to change inventorship on still-pending applications. Astellas' motion should be denied, and this Court should enter ImStem's proposed judgment. D.I. 265, Ex. A.

II. ARGUMENT

A. ImStem Never Represented That The PCT Application's Claims Are The Same As The '551 Patent's Claims

Astellas asserts that ImStem argued before the FFCL that the "***entire disclosure*** (examples, figures, ***claims***) of the '551 patent" was identical to that in the PCT application. D.I. 268 at 6 (citing ImStem's post-trial brief, D.I. 247-1 ¶ 134). But Astellas' argument is belied by the source it cites, wherein ImStem stated only that the "PCT Application was the basis for the

'551 national stage and thus has the same ***specification and figures*** as the '551 patent."[1] D.I. 247-1 ¶ 134 (emphasis added). ImStem made no such statement as to the ***claims***.

In fact, the claims are different. As ImStem explained (D.I. 265 at 10), comparison of the PCT application and the '551 patent demonstrates that they differ in the number of claims recited. The additional claims in the PCT application are also directed to subject matter absent from the claims of the '551 patent, as ImStem noted in its opposition without response from Astellas. D.I. 265 at 10. For example, the PCT application discloses "methods of using the human embryonic stem-cell derived mesenchymal stem cells for the delivery of agents across the blood brain barrier and the blood spinal cord barrier" and "methods of using hES-MSCs to . . . repair damaged central nerve systems." Trial Ex. 40 at AIRM00293508, 293816. Because inventorship is determined on a claim-by-claim basis (a point Astellas does not dispute, D.I. 268 at 7-8), the Court's inventorship determination in the FFCL applies only to the eleven claims of the '551 patent (and the eleven claims of the '122 patent by stipulation). The Court has never considered the contributions of Drs. Lanza, Kimbrel, Wang and Xu to each claim of the PCT application because such a determination was not pertinent to the issues Astellas timely raised. Nor has the Court considered Drs. Wang's and Xu's contributions to each claim of any of the other patents and applications encompassed by Astellas' proposed judgment.

B. ImStem Did Not Mischaracterize The Factual Disputes Raised By Astellas' Proposed Judgment

According to Astellas, "Defendants' examples purporting to show the '551 PCT Application and its related applications and patents present factual disputes not already decided by

[1] ImStem did not make this statement to support its argument that Drs. Wang and Xu are inventors on the '551 patent, but rather to demonstrate that, as of the 2013 filing date of the PCT application, Astellas was aware of the subject matter in the '551 patent. *See* D.I. 247-1 ¶¶ 131-140; *see also* D.I. 221 ¶¶ 62-69.
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this Court show no such thing." D.I. 268 at 7. Astellas points to two examples of issues this Court decided, which, according to Astellas, resolve every factual issue raised by its proposed judgment. *See id.* at 8-9. But Astellas speaks in generalizations that disregard the specifics of the patents and applications encompassed by its proposed judgment.

Astellas argues that the Court already determined that Dr. Lanza had the idea to use ***HB-MSCs in general*** to treat autoimmune diseases. *Id.* at 8. But Astellas never addresses ImStem's point (D.I. 265 at 10-12) that the PCT application includes claims directed to the additional subject matter referenced above, *see supra* Section II.A; nor does Astellas confront that the PCT's specification discloses additional ideas and steps beyond those recited in the '551 patent's claims.

Astellas also argues that ImStem "omit[ted]" facts regarding the '944 application that, according to Astellas, were already "considered and resolved." D.I. 268 at 9. But it is Astellas that omits key distinctions between the '944 application and the '551 patent. For example, the currently pending claims of the '944 application recite "disassociating" the embryonic stem cells into "aggregates." D. I. 268, Ex. A at 5. This is clearly different from the '551 patent's claim element of "disaggregating the hemangio-colony forming cells . . . into single cells." Trial Ex. A (Claim 1). The new claims also require the use of an "ultra-low-attachment dish," D.I. 268, Ex. A at 5, a term absent from the '551 patent's claims or the FFCL.

In addition to the distinctions between the claims of the '551 patent relative to the '944 application, the '944 application is still pending, and thus its claims may continue to change throughout prosecution. The same is true of the currently pending Canadian and Hong Kong applications. *See* D.I. 265 at 12. As ImStem explained (D.I. 265 at 11-12), but Astellas ignored, an inventorship determination for those applications is therefore premature.

C. ImStem Correctly Distinguished *Chou v. Univ. of Chicago*

Astellas asserts that "*Chou*'s language is not dicta or 'moot'" (D.I. 268 at 10), but Astellas disregards the Federal Circuit's own statement that the "declaratory judgment claim for correction of inventorship … is moot." *Chou v. Univ. of Chicago*, 254 F.3d 1347, 1366 (Fed. Cir. 2001).

To be sure, *Chou* involved both a (moot) declaratory judgment claim and a claim under 35 U.S.C. § 256. But as to the latter, *Chou* did not address a situation where, as here, the deadline to change inventorship on a PCT application had expired. D.I. 265 at 18. Nor did *Chou* hold that inventorship on PCT applications ***always*** follows the inventorship designation in the originating country. *Chou* stated that, because inventorship on PCT applications "***normally*** follows the inventorship designation in the originating country" the district court could instruct Defendant to change the inventors listed on those applications "***if*** it conclude[d] . . . that Chou is properly an inventor." 254 F.3d at 1360 (emphasis added). Moreover, *Chou* concerned, at most, the district court's authority to change inventorship on PCT applications, not on foreign patents and applications more generally (such as the Chinese patent owned by non-party Zhuhai ImStem).[2]

D. The Court Correctly Concluded That Astellas' Cannot Prove Actual Economic Harm, Precluding Recovery under Chapter 93A

According to Astellas, its current claim under Chapter 93A is distinct from the one it brought at trial because it is based on ImStem's alleged post-trial refusal to "return the related applications, despite the inventorship findings of this court." D.I. 268 at 12. But even if the other applications were related in any legally relevant way (they are not), they would not give rise to a claim under Chapter 93A, just as the '551 patent did not at trial.

[2] Astellas does not confront its failure to demonstrate at trial that Defendants control Zhuhai ImStem such that they could force a correction of ownership of Zhuhai ImStem's patent. D.I. 265 at 15-16. Astellas also does not contest that applying an inventorship determination based on U.S. patent law to foreign patents and applications would violate the presumption against extraterritoriality. D.I. 268 at 11 n.6.

As the Court explained in its FFCL, in order to prove a violation of Chapter 93A, Astellas had to establish that "the defendant . . . committed an unfair or deceptive act" ***and*** "a loss of money or property suffered as a result." D.I. 255 at 44-45 (quoting *Auto Flat Car Crushers, Inc. v. Hanover Ins. Co.*, 17 N.E.3d 1066, 1074-75 (Mass. 2014)). Even if Astellas' allegations about ImStem's post-trial conduct are true, they would affect at most the first element, not the second, which this Court already resolved in Defendants' favor in the FFCL.

Massachusetts law is clear: "Speculation concerning still inchoate harm does not establish the distinct injury that 'is an essential predicate for recovery under' Chapter 93A." *Shaulis v. Nordstrom, Inc.*, 865 F.3d 1, 10 (1st Cir. 2017) (citation omitted). Based on the trial record, the Court found that "Astellas was unable to demonstrate lost sales in connection with Defendants' conduct" and that "Astellas was unable to demonstrate concrete or lasting effects from Defendants' actions." D.I. 255 at 46. Astellas does not argue that the facts regarding economic harm have changed since trial. Instead, Astellas contends that both parties are "continuing efforts to develop MSCs as therapies," but that "these efforts take time to complete clinical trials and to receive regulatory approval." D.I. 268 at 13. Such allegations are the definition of "inchoate harm," and this Court correctly concluded that such inchoate "harms" do not give rise to a claim under Chapter 93A. Even to the extent such harm could theoretically be proved in a non-speculative way, the time for Astellas to do so was at trial, not after.[3]

III. CONCLUSION

The Court should deny Astellas' Motion and instead enter a final judgment paper in the form of Exhibit A.

[3] Astellas does not contest that, if the Court chose to revisit its Chapter 93A conclusions, the Court would also need to address Defendants' statute of limitations and unclean hands defenses. *See* D.I. 268 at 13.

Dated: June 22, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 22, 2021 I caused a true copy of the foregoing document to be served upon all counsel of record via the Court's CM/ECF electronic filing system.

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